

REMARKS

Reconsideration is requested.

Claims 78-140 are pending. The details of claim 87 have been included in claim 78. No new matter has been added.

The Section 112, second paragraph, rejection of claims 78 and 136-137¹ is obviated by the above amendments. Withdrawal of the rejection is requested.

The Section 112, first paragraph "written description", rejection of claims 138-140 is traversed.² Reconsideration and withdrawal of the rejection are requested in view of the following comments.

The Examiner is understood to believe that the specification "lacks description of "hydrates"." The applicants believe that one of ordinary skill will appreciate that the hydrates of the claims includes all possible hydrates and is therefore clear. The various hydrates can be prepared with reasonable experimentation. The term is accepted in the art and has been widely used and accepted in the patent literature.

With regard to the Examiner's comments relating to claim 138-140, the Examiner is understood to believe that the applicants have not shown a nexus for the inhibition of telomerase in vitro or in vivo and treating or preventing diseases.

To the extent the Examiner is requiring a demonstration of clinical efficacy based on pre-clinical data, the applicants submit that demonstration of clinical efficacy is not a

¹ While the statement of the rejection only includes claims 78 and 136-137, the Examiner's further comments under the statement of the rejection include criticisms of claims 87, 110-118, 120-123 and 129. A complete statement of any rejection in the event any rejections are maintained is requested for clarity of the record.

² While the statement of the rejection on pages 3-4 of the Office Action dated March 14, 2006, only includes claims 138-140, the Examiner's further comments under the statement of the rejection

requirement of the Patent Law. Moreover, the Examiner is requested to see the attached Johnson et al (British Journal of Cancer (2001) 84(10), 1424-1431) which demonstrates that clinical efficacy can be predicted based on *in vitro* tests. Specifically, the attached reference demonstrates a correlation between positive results in *in vitro* models and clinical trials *in vivo*.

Further, the Examiner is requested to see the applicants copending U.S. Patent Application Publication No. US 2003-0207909 A1, copy attached, which demonstrates that inhibition of telomerase *in vitro* relates to activity *in vivo* for treating cancer. The pending, allowed claims of the published application are available to the Examiner from the USPTO PAIR however the Examiner is requested to advise the undersigned in the event a further copy is required to be separately submitted.

Withdrawal of the Section 112, first paragraph "written description", rejection of claims 138-140 is requested.

The Section 112, first paragraph "enablement", rejections of claims 138-140 is traversed. Reconsideration and withdrawal of the rejection are requested as one of ordinary skill in the art would be able to make and use the invention of the rejected claims. Specifically, for example, the attached Johnson et al, demonstrates that clinical efficacy can be predicted based on *in vitro* tests. Moreover, the attached copending U.S. Patent application provides evidence that inhibition of telomerase *in vitro* relates to activity *in vivo* for treating cancer. The level of skill in the art is advanced and no more

include criticisms of claims 78 and 136. A complete statement of any rejection in the event any rejections are maintained is requested for clarity of the record.

than reasonable experimentation would be required to make and use the invention of the rejected claims.

Withdrawal of the Section 112, first paragraph "enablement", rejections of claims 138-140 is requested.

The Section 102 rejection of claims 78, 80, 82, 84-86, 88, 112, 130 and 132-133 over Gamage (Journal of Medicinal Chemistry, Vol. 37, pages 1486-1494) is obviated by the above amendments. Withdrawal of the Section 102 rejection is requested.

The Section 103 rejections of claims 78, 79, 82, 84-86, 88, 130, 132 and 133 over McConnaughie et al (Journal of Medicinal Chemistry, vol 38, pages 2488-501) or Read (PNAS, Vol. 98, pages 4844-4849) in view of Gamage, are traversed. Reconsideration and withdrawal of the rejections are requested in view of the following distinguishing comments.

Gamage is understood to disclose topoisomerase II inhibitors while Read is understood to disclose telomerase inhibitors and McConnaughie is understood to disclose DNA minor-groove binders.

The primary references of the rejections are further understood to disclose an intermediate compound wherein an acridone has unsubstituted amine groups attached at the 3 and 6 positions. It appears to the applicants that the Examiner considers that di-substitution of the amino groups with methyl substituents would, in light of the disclosure of the secondary reference, allegedly have been obvious.

The Examiner is requested to appreciate however that the compounds cited by the Examiner in Read, which is the only telomerase-related document of the rejection, are early intermediates that were not tested for biological activity. Moreover,

McConnaughie and Gamage do not teach or suggest compounds that can inhibit telomerase. There was no motivation in the art to have combined the references and combination of references would not have led one of ordinary skill in the art to have made the presently claimed invention.

Withdrawal of the Section 103 rejections is requested.

The applicants acknowledge, with appreciation, the Examiner's indication of allowable subject matter. Allowance of all of the claimed subject matter is requested.

The Examiner is requested to contact the undersigned in the event anything further is required.

Respectfully submitted,

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